72-1593

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In The
SUPREME COURT OF THE UNITED STATES
October Term, 1972

72-1593

LABEL, INC.
Petitioner

v.

SHERWIN GARDNER, Acting Commissioner,
Food and Drug Administration
and
THE FOOD AND DRUG ADMINISTRATION
Respondents

PETITION FOR A WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

John Banzhaf III
2000 H Street N.W.
Washington, D.C. 20006

James S. Turner
Suite 600
910 16th Street N.W.
Washington, D.C. 20006

Arthur D. Koch
2020 F Street N.W.
Washington, D.C. 20006

Attorneys for Petitioner

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LABEL, Inc. petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case

OPINION BELOW

The opinion of the Court of Appeals (Appendix A, infra) was rendered in the form of a Judgment and is not reported.

JURISDICTION

The judgment of the United States Court of Appeals for the District of Columbia Circuit was entered March 1, 1973. The jurisdiction of this Court is invoked under 28 U.S.C. §1254(1).

QUESTION PRESENTED

Whether the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et. seq. grants the discretionary authority to permit the promulgation of a substantive rule by the Food and Drug Administration that would require manufacturers or distributors of food products to list on the label all of the ingredients (except flavors, spices, and colors) that are contained in a product.

STATUTE INVOLVED

The statute involved is the Federal Food, Drug, and Cosmetic Act of 1938, as amended, 21 U.S.C. §301 et. seq. The pertinent sections of that Act are set forth in Appendix C, infra.

STATEMENT

On February 25, 1971, LABEL, Inc. (the Law students Association for Buyers' Education and Labeling) filed a petition with the Food and Drug Administration requesting that the agency issue a

regulation under Section 701(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §371(e)(1)(B), which would state:

> For the purposes of promoting honesty and fair dealing in the interest of the consumer, all food manufacturers and distributors must list on the label, in the order of their predominance, all ingredients which are contained in their product.

In response to this petition, a notice of proposed rule making was published in the Federal Register of May 12, 1971, 36 F.R. 8738. The Commissioner of the Food and Drug Administration invited interested persons to submit their comments on the matter. On the request of LABEL, Inc. and by further notice published in the Federal Register of July 14, 1971, 36 F.R. 13100, the time for filing comments was extended to August 10, 1971.

An unprecedented four to five thousand comments from industry and consumers were received by the Food and Drug Administration. The overwhelming majority of these comments (about 95%) were in favor

of the LABEL proposal, while only two to three hundred food companies objected.

A year and a half after the close of the comment period, the Food and Drug Administration denied the LABEL proposal stating:

> The Commissioner, having evaluated the comments and other relevant material, concludes that he does not have legal authority to promulgate the requested regulation and that the petition must therefore be denied. 37 F.R. 5131 (Appendix B, infra.)

The Commissioner and the Food and Drug Administration, however, openly agreed with the need and desire for such a regulation as that proposed by LABEL, Inc. In the same issue of the Federal Register containing the denial of the LABEL petition, the Food and Drug Administration issued the following Statement of General Policy or Interpretation:

> There is significant consumer interest that the labels of standardized foods bear complete information of the ingredients contained in the food. In the absence of legal authority to require

> that the label bear such information, the Food and Drug Administration encourages all manufacturers, packers, and distributors to voluntarily make such disclosure. 37 F.R. 5120, March 10, 1972.

Having exhausted its administrative remedies, LABEL, Inc. (joined by the National Health Federation) petitioned the United States Court of Appeals for the District of Columbia to review and reverse the restrictive interpretation of the Federal Food, Drug, and Cosmetic Act that was made by the Food and Drug Administration. On March 1, 1973, the Court of Appeals affirmed the decision of the agency.

LABEL, Inc. contends that the Federal Food, Drug, and Cosmetic Act provides ample authority to permit the Commissioner of the Food and Drug Administration to issue a regulation that would require complete ingredient labeling of all food products. LABEL, Inc. is not arguing here what the Food and Drug Administration <u>should</u> do --- LABEL, Inc. and the Food and Drug Administration both agree that more complete ingredient labeling is absolutely necessary. Rather, the sole question that the Petitioner raises here is whether or not there is authority

for the Food and Drug Administration to act in this direction.

REASONS FOR GRANTING THE WRIT

(1) The Court of Appeals has Misconstrued a Major Decision of the Supreme Court

The Court of Appeals erred in its construction of Federal Security Administrator v. Quaker Oats Co., 318 U.S. 218 (1943), a major decision of the Supreme Court, and relied on its interpretation to justify its decision that the Food and Drug Administration does not have the authority to require the listing of all ingredients contained in a standardized food product.

In Federal Security Administrator v. Quaker Oats Co. the Supreme Court held that a food manufacturer could not deviate from a promulgated standard of identity even if he were to label the package truthfully. The Court did not say that if the company complied with the standard of identity, it still could not list all the ingredients. The Court was concerned with the addition of an ingredient to a product when the standard of identity did not list that ingredient. Truthfully labeling such an additional ingredient, the Court reasoned, did not make the addition of that ingredient permissible. The standard of identity

had to be followed.

No change would result in the Quaker Oats situation if the FDA were to issue a regulation requiring complete ingredient labeling. The fact that ingredients would have to be listed would not authorize food manufacturers of standardized products to add whatever ingredients they desired. As the Court held in Quaker Oats, the manufacturer would still be bound by the ingredients dictated in the standard of identity. The crucial difference is that the consumer would also be able to discover what the FDA had determined to be permissible and what combination of these ingredients the food manufacturer had chosen.

The Holding of Quaker Oats was no more than that the structure set up by Congress did not then require informative labeling of standardized foods:

> Both the text and the legislative history of the present statute [Federal Food, Drug and Cosmetic Act] plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from "economic

> adulteration," by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold. 318 U.S. 230.

Quaker Oats therefore does not indicate a judicial recognition of an absence of Congressional intent or authority to require ingredient labeling. Rather, limited to its facts, it suggests that the Act's purpose was to authorize the FDA to promulgate standards of identity "under which the integrity of food products can be effectively maintained." 318 U.S. 230.

> (2) The Misinterpretation of The Quaker Oats Case Rests on and has Caused Confusion Regarding Ingredient Labeling of Food Products

When LABEL, Inc. petitioned the Food and Drug Administration to issue a regulation requiring complete ingredient labeling of food products, the FDA

answered that though it would like to, 37 F.R. 5120 (March 10, 1972), it could not do so because it lacked the legal authority to act, 37 F.R. 5131 (March 10, 1972). The Food and Drug Administration further claimed that while it could not require the listing of the mandatory ingredients of standardized food products, it would require the "label declaration of all optional ingredients with the exception of optional spices, flavorings, and colorings." 37 F.R. 5120 (March 10, 1972) Under such circumstances, the consumer should be able to determine the content of a food product by reading the list of mandatory ingredients in the Code of Federal Regulations (Volume 21, Part 1 to Part 119) and noting the optional ingredients on the package label.

Although the Court of Appeals thought this to be the situation, such is not the case.* In addition to simple mandatory

* The confusion over these aspects of the labeling requirements of the Federal Food, Drug, and Cosmetic Act was evident when, during the oral argument, the Court asked the government to prepare a memorandum on why some food ingredients were permitted to be used as permissible mandatory ingredients in some food standards. When it was suggested by by government Counsel that this was the case only for flavors, colors, and spices, the Court withdrew

and optional ingredients, there is a classification of ingredients which LABEL, Inc. has chosen to call "Permissible Mandatory Ingredients." These are ingredients that are listed by group in the mandatory category within the standard of identity, at least one of which (but not all) must be in the product. This means that of those ingredients listed as "mandatory" in the standard of identity, only some of them are actually contained in the product. If they are contained in the product under this group, they do not have to be labeled and the FDA claims that they cannot be required to be listed. Such labeling is one of the issues of this case.

Thus, for example, the standard of identity for canned peaches, 21 CFR 27.2, states that <u>one</u> of the following packing media must be contained in the product:

water
peach juice
slightly sweetened water
light sirup
heavy sirup

---

its request. However, as is pointed out above, such special classifications exist for a variety of ingredients other than merely flavors, colors, and spices in many food standards. The government should now be placed in a position to provide an answer to the Court's question.

extra heavy sirup
slightly sweetened peach juice
light peach juice sirup
heavy peach juice sirup
extra heavy peach juice sirup

Since the inclusion of one of the above is "mandatory," the company can use water as compared to the other choices and not indicate that choice on the label. Other common examples of this situation include the mandatory choice of "sweetening ingredients" (sugar (sucrose) or sugar sirup, dextrose, invert sugar (in paste or sirup form), corn sirup, dried corn sirup, glucose sirup, dried glocose sirip, maple sirup, maple sugar, honey, brown sugar, malt sirup, maltose sirup malt extract, dried malt sirup, dried maltose sirup, dried malt extract, refiner's sirup, molasses (other than blackstrap), lactose, and Fructose N.F.) in ice cream, 21 CFR 20.1, acidifying ingredients (Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mised with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of citric acid is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more

vinegars is considered to be a vinegar. Lemon juice or lime juice or both or any such juice in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water to an acidity, calculated as citric acid, of not less than 2½ percent by weight) in mayonnaise, 21 CFR 25.1, and "one of the optional saccharin ingredients" (1. sugar; 2. invert sugar sirup; 3. any combination composed of optional saccharine ingredients 1 and 2; 4. any combination composed dextrose and optional saccharine ingredients 1, 2, or 3; 5. any combination composed of corn sirup, dried corn sirup, glucose sirup, dried glocose sirup, or any two or more of the foregoing with optional saccharine ingredient 1, 2, 3, or 4 in which the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glocose sirup, or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-forth of the total weight of the solids of the combined saccharine ingredients; 6. honey; 7. Any combination composed of honey and optional saccharine ingredient 1, 2, or 3, in which the weight of the solids of each component except honey is not less than one-tenth of the weight of the solids of such combination and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination) in

preserves and jams, 21 CFR 29.3.

In addition, as recently as January, 1973, the Food and Drug Administration said that inorder to effectuate the proposed nutritional labeling program, they had the authority to require the listing of some mandatory ingredients:

> All food standards providing for addition of nutrients or labeling of nutritional aualities have been reviewed. For most food standards, the addition of nutrients is optional and nutrition labeling is therefore entirely appropriate because the manufacturer is not required to add nutrients or to label nutritional properties. For those few food standards where the addition of nutrients and/or the labeling of nutritional properties is mandatory, the Commissioner has concluded that no hardship will be imposed by the application of nutrition labeling. Accordingly, none of these standardized foods is exempted from nutrition labeling. 38 F.R. 2125 (January 19, 1973) /Emphasis Added/

The Food and Drug Administration has

thus been contradictory in its interpretation of the question of whether or not it has the authority to require the labeling of mandatory ingredients of standardized food products.

The FDA argued in court that it could not require such labeling. Yet, in the Federal Register statement, the FDA has initiated a "hardship" standard. It is respectfully suggested that the agency cannot declare it has authority to do something when it wants to and deny such authority when it does not want to use it.

The single question presented before the Circuit Court and now before this Court is whether or not such authority exists. Petitioner clearly understands that the discretion to use that authority is another matter and is in the hands of the agency.

(3) The Question of Complete Ingredient Labeling of Food Products is Important to the Entire Consuming Public

According to present Food and Drug Administration regulations, many food manufacturers and distributors are exempted from telling the consumer all of the ingredients that they add to the foods they produce and sell. Thus, although most food packages contain an ingredient listing, many of these listings are incomplete and often fail

to identify potentially harmful ingredients that are contained in the product. Consumers, assuming that such listings must be complete, are constantly being misled and have no way of knowing whether or not a particular ingredient listing is complete or partial.

This confusing state of affairs literally affects every household in America and is especially dangerous to those people who are carefully watching what they are eating. Such people are falsely being led to believe that they know what they are eating when , in fact, they have no way of determining the complete content of many foods. This is inexcusable when one considers the millions of Americans with food allergies and the millions of Americans who are scrutinizing their diets because of varried heart conditions or other health factors.

This problem was most dramatically brought to light when it was reported in June, 1972 that a ten year old child who had an allergy to peanuts, carefully read the label of an ice cream package. Not finding peanuts listed, the child ate the ice cream. Within a matter of hours, the child died from a reaction due to the consumption of unidentified peanuts in the ice cream.

Numerous other consumers are concerned about the potentially harmful additives and other ingredients that are being put in our foods. These consumers are trying

to avoid such potential dangers, but can't do so because the Food and Drug Administration does not require complete ingredient disclosure. Further, millions of consumers wish to carefully watch the foods they eat for a variety of religious reasons, but again cannot do so, and in many cases, are being misled by the incomplete ingredient listings that currently appear on many food products.

In sum, the lack of complete ingredient labeling probably touches the lives of every consumer everyday. The fact is that almost every time a consumer reads an ingredient listing on a food product, the chances are good that he is being misled. While both the FDA and the Petitioner agree that the situation should be corrected, the FDA claims they do not have the necessary authority to act. Petitioner, on the other hand, argues that there is ample authority in the Federal Food, Drug, and Cosmetic Act for the Agency to act.

(4) The Purpose of the Federal Food, Drug, and Cosmetic Act is not being Carried Out

As has been pointed out briefly, the consuming public has a strong need to know the content of the foods they eat. However, under the current regulations, the Food and Drug Administration has made it impossible for the consumer to get this information.

It is respectfully suggested that Congress intended that the Federal Food, Drug, and Cosmetic Act be a tool to protect the consumer, rather than an excuse to conceal valuable information that is continuously hindering people who wish to follow various restricted diets. As the Supreme Court noted in United States v. Dotterweich, 320 U.S. 280 (1943):

> The purposes of this legislation [the Federal Food, Drug, and Cosmetic Act] thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government, and not merely as a collection of English words.

While remaining within the bounds of the Act, the Courts -- and especially the Supreme Court, have always construed the Federal Food, Drug, and Cosmetic Act liberally so as to allow the Food and Drug Administration to effectively protect the consuming public. In the present

case, the Food and Drug Administration admits that more complete ingredient labeling of food products is necessary for consumer protection. However, feeling restrained by their own interpretation of the Act (as affirmed by the Court of Appeals), they have requested that manufacturers voluntarily comply. This is not a solution to the problem and unfortunately has resulted in an even more confusing state of affairs for the consumer.

(5) The Broad Language of the Federal Food, Drug, and Cosmetic Act Contains Ample Authority for the Agency to Act

Section 403(a) of the Act, 21 U.S.C. 343(a) empowers the Food and Drug Administration to declare a food misbranded "if its labeling is false or misleading in any particular." Since numerous consumers are being mislead by the current system of partial ingredient listings on standardized foods, Petitioner contends that the clear mandate of the Congress in the above section and the grant of rule making power in Section 701(a) of the Act, 21 U.S.C. 371(a), authorizes the Commissioner to act in such cases.

The Commissioner, however, has chosen to look to Section 403(g) of the Act, 21 U.S.C. 343(g), as controlling:

> A food shall be deemed to be misbranded --
> (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

Petitioner contends that while Section 403(g) requires only the listing of optional ingredients of standardized foods, it does not prohibit the listing of all ingredients. In addition to arguing under Section 403(a), Petitioner wishes to point out the clear language of Section 201(n) of the Act, 21 U.S.C. 321(n):

> If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by

> statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Petitioner respectfully requests that the confusing and conflicting relationships of these sections of the Act be clairified.

CONCLUSION

For the foregoing reasons it is respectfully submitted that the writ of certiorari requested hereby should be issued and the opinion and judgment of the Court of Appeals reversed.

Respectfully submitted,

John Banzhaf III

James S. Turner

Arthur D. Koch
Attorneys for Petitioner

May 29, 1973

APPENDIX A

JUDGMENT AND MEMORANDUM
OF THE COURT OF APPEALS

UNITED STATES COURT OF APPEALS
For The District Of Columbia Circuit

No. 72-1510

LABEL, Inc. et al
Petitioners

v.

Charles C. Edwards, Commissioner
Food and Drug Administration and
The Food and Drug Administration
Respondents

Petition For Review Of An Order
Of The Food And Drug Administration

Before: Leventhal and Robb, Circuit Judges, and Charles Richey (sitting by designation pursuant to 28 U.S.C. §292(a)) United States District Judge for the District Court for the District of Columbia

JUDGMENT

This case came on to be heard on a Petition for Review of an Order of the Food and Drug Administration and the Court heard argument of counsel. On consideration of the foregoing, it is ORDERED AND ADJUDGED by this Court that the order of the Food and Drug Administration is hereby affirmed for the reasons set forth in the attached memorandum.

Per Curiam
For the Court

Hugh E. Kline
Clerk

MEMORANDUM

This appeal is before us on a petition of review under the Food, Drug, and Cosmetic Act, on the action of the Food and Drug Administrator rejecting a regulation under Section 701(e)(1)(B) by Label, Inc. concerning disclosure on the label of all ingredients contained in standardized and nonstandardized foods. The Food and Drug Administrator has express authority to require information on the label as to all optional ingredients of food products for which the Administrator has promulgated definitions and standards of identity. The Administration has announced its

intention to exercise this authority to the utmost, and to seek at the same time legislation that would specify its authority to promulgate substantive rules requiring effective information to the consumer of composition of standardized foods, even as to mandatory ingredients. The agency does not dispute the objectives of the type of labeling sought by petitioners. Given the language of Section 403(g) of the Food, Drug and Cosmetic Act, 21 U.S.C. 343(g), and the references in Federal Security Administrator v. Quaker Oats, 318 U.S. 218 (1943) we cannot say that the Commissioner erred in determining to deny the petitioners' proposal, and to seek enactment of legislative provisions expressly setting forth pertinent authority.

Affirmed.

APPENDIX B

FDA DENIAL OF PETITION BY LABEL, INC. 37 F.R. 5131 MARCH 10, 1972

LABEL DECLARATIONS ON STANDARDIZED AND NONSTANDARDIZED FOODS

Notice of Denial of Petition

A notice of proposed rule making was published in the FEDERAL REGISTER of May 12, 1971 (36 F.R. 8738), in response to a petition filed by Label, Inc., concerning disclosure, on the label, of all ingredients contained in standardized and nonstandardized foods. By notice published in the FEDERAL REGISTER on July 14, 1971 (36 F.R. 13160), time for filing comments on the proposal was extended to August 10, 1971.

The Commissioner of Food and Drugs also invited comments on whether the Federal Food, Drug, and Cosmetic Act provided the legal authority to promulgate the proposed regulation, or whether new legislation must be enacted.

More than 4,000 comments were received from consumers, consumer groups, the medical and scientific community, State and local governments, the food industry, trade associations, and others. Most of them favored ingredient disclosure. Some comments included a discussion of the legal issues involved.

The Commissioner, having evaluated the comments and other relevant material, concludes that he does not have legal authority to promulgate the requested regulation and that the petition must therefore be denied, as follows:

1. The statutory language of sections 401 and 403 (g) and (i) of the act defines two categories of food: Standardized and nonstandardized. Congress explicitly provided distinct labeling requirements for each category. It specifically and deliberately did not require that all foods be labeled with a list of all ingredients. For example, the statute requires that the label of a nonstandardized food that is fabricated from two or more ingredients

must bear the common or usual name of each ingredient, except that spices, flavorings, and colorings do not have to be named on the label unless they are sold as such. For standardized food, the statute requires that the label must bear only the common name of each optional ingredient (other than spices, flavoring, and coloring) included in the definition and standard of identity and specifically designated in the standard to be named on the label. Failure to comply with these labeling requirements is a misbranding violation. There is no statutory authority to require that the label bear the name of each mandatory ingredient contained in a standardized food or the name of each spice, flavoring, or coloring contained in any food. If Congress had intended to require full disclosure of all ingredients contained in all food, instead of different labeling requirements for different foods, it would have so provided in the statute.

2. The lack of statutory authority to require complete ingredient disclosure is clearly indicated by the statute's legislative history and confirmed by the decision of the U.S. Supreme Court in Federal Security Adm'r v. Quaker Oats Co., 318 U.S. 218 (1943).

Accordingly, for the foregoing reasons the petition of Label, Inc. is denied.

Although the Commissioner lacks legal authority to require complete ingredient disclosure, there is nothing in the act prohibiting manufacturers, packers, and distributors from voluntarily making such disclosure, and there is published elsewhere in this issue of the FEDERAL REGISTER, a notice to that effect.

This action is taken pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 401, 403, 701; 52 Stat. 1046, 1047, 1055, as amended; 21 U.S.C. 341, 343, 371) and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: March 3, 1972.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.72-3657 Filed 3-9-72;8:46 am]

APPENDIX C

TEXT OF PERTINENT SECTIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT (As Amended, August, 1972)

The Act Appears in the United States Code Under Title 21. Corresponding Section Numbers of the Code Appear in Brackets After the Section Number of the Act.

SEC. 201 [321]. For the purposes of this Act—

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

DEFINITIONS AND STANDARDS FOR FOOD

SEC. 401 [341]. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocados, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocados, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

MISBRANDED FOOD

SEC. 403 [343]. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

REGULATIONS AND HEARINGS

SEC. 701 [371]. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

In the Supreme Court of the United States

OCTOBER TERM, 1973

No. 72-1593

LABEL, INC., PETITIONER

v.

SHERWIN GARDNER, ACTING COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

MEMORANDUM FOR THE RESPONDENTS IN OPPOSITION

Petitioner seeks review of a decision holding that the Federal Food, Drug, and Cosmetic Act does not authorize the promulgation of a substantive rule requiring manufacturers and distributors of standardized foods to list all ingredients on the label of their products.

1. By petition filed on February 25, 1971, petitioner requested the Food and Drug Administration to issue the following substantive regulation:

> For the purposes of promoting honesty and fair dealing in the interest of the consumer, all food manufacturers and distributors must list on the label, all ingredients which are contained in their product.[1]

[1] The proposed rule is partially redundant since ingredient labeling of nonstandardized foods is already required by Section 403(i) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 343(i).

The Commissioner of Food and Drugs published the petition in the Federal Register on May 12, 1971, and invited comments by interested persons on the proposed rule and his authority to issue it. 36 Fed. Reg. 8738. After the comments were reviewed and evaluated, the Commissioner published an order in the Federal Register of March 10, 1972, denying the petition on the ground that he lacked the authority to promulgate the requested regulation. 37 Fed. Reg. 5131.[2]

Petitioner sought review of the agency order in the United States Court of Appeals for the District of Columbia Circuit. The court of appeals affirmed *per curiam* (Pet. App. 1a-3a).

2. The decision below is correct and the petition for certiorari raises no question warranting further review.

Petitioner asserts that Section 701(a) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 371(a), authorizes the issuance of the substantive rule requested. Section 701(a) provides:

> The authority to promulgate regulations *for the efficient enforcement of this Act*, except as otherwise provided in this section, is hereby vested in the Secretary. [Emphasis added.]

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[2] At the same time, because of his agreement with the objective of the petition and the significant consumer interest involved, the Commissioner promulgated a statement of policy encouraging all manufacturers, packers and distributors of standardized foods voluntarily to make such disclosures. 21 C.F.R. 3.88. Additionally, the Commissioner recommended legislation authorizing the agency to require full ingredient labeling of standardized foods. A bill to that effect was introduced in the ninety-second Congress, H.R. 14641, and reintroduced in the ninety-third Congress, S. 1451 and H.R. 5642.

This Section empowers the Secretary to issue substantive rules to construe, interpret and apply existing statutory provisions. It does not, however, authorize him "to alter or add to" the regulatory scheme adopted by Congress. *United States* v. *Antikamnia Co.*, 231 U.S. 654, 666.

The Federal Food, Drug and Cosmetic Act designates two classes of foods—standardized and nonstandardized —and establishes different ingredient labeling requirements for each.[3] These requirements are set forth in Section 403 of the Act, 21 U.S.C. 343, which provides in pertinent part:

> A food shall be deemed to be misbranded—
>
> * * * * *
>
> (g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients * * * present in such food.
>
> * * * * *
>
> (i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there

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[3] Standardized foods are those for which regulations have been promulgated by the Commissioner establishing "a reasonable definition and standard of identity, a reasonable standard of quality and/or reasonable standards of fill of container." Section 401 of the Act, 21 U.S.C. 341. All other foods are nonstandardized.

> be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient * * *.

In *Federal Security Administrator* v. *Quaker Oats Co.*, 318 U.S. 218, 230, this Court analyzed Section 403 of the Act, explaining:

> Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. * * * Rather it was the purpose to authorize the Administrator to promulgate definitions and standards of identity "under which the integrity of food products can be effectively maintained," * * * and to require informative labeling only where * * * the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label. [Citations omitted.]

Congress, in the Federal Food, Drug, and Cosmetic Act, could have required full ingredient labeling of all foods, but it adopted instead the "standard of identity" regulatory scheme embodied in Sections 403(g) and (i). See *Quaker Oats Co., supra,* 318 U.S. at 232. Given the language and purpose of the statute, the Commissioner may not by administrative rulemaking substitute his judgment for that of the legislature. Only Congress, not the Commissioner, may revise the law. Accordingly, the Commissioner properly concluded that he lacked the authority to issue the regulation requested.

It is therefore respectfully submitted that the petition for a writ of certiorari should be denied.

ROBERT H. BORK,
Solicitor General.
THOMAS E. KAUPER,
Assistant Attorney General.

PETER BARTON HUTT,
Assistant General Counsel,
Department of Health, Education and Welfare.

JULY 1973.